CLAIMS

1. A solid, oral, controlled release pharmaceutical dosage form which comprises a pharmaceutically active ingredient having a solubility in water of greater than 1gm in 250ml water at 25°C dispersed in a matrix and wherein the dosage form when tested by the Ph. Eur. Basket method at 100 rpm 900 ml aqueous buffer (pH 6.5) containing 0.05% w/w Polysorbate 80 at 37°C has an essentially zero order rate of release of the pharmaceutically active ingredient over a period of 8 hours, the amount of pharmaceutically active ingredient released over eight hours being in the range of 15% to 45%, and when tested in a group of at least five healthy humans the median tmax, based on blood sampling at half hourly intervals, is in the range of from 2.5 to 6 hours, and the ratio of mean Cmax to the mean plasma level at 24 hours is in the range of 1.5 to 3.5.

2. A pharmaceutical dosage form according to claim 1, wherein the median tmax is in the range from 2.5 to 3.5 hours.

3. A pharmaceutical dosage form, according to any one of the preceding claims which has a W_{50} in the range from 15 to 35 hours, preferably from 20 to 30 hours, when tested in vivo as set forth in claim 1.

4. A pharmaceutical dosage form according to claim 1, 2 or 3, wherein the matrix comprises a mixture of an hydrophobic, fusible material having a melting point of greater than 40°C and a hydrophilic, organic, polymeric fusible wicking agent.

5. A pharmaceutical dosage form according to any one of claim 4 wherein the weight ratio of hydrophobic fusible material to hydrophilic, organic polymeric wicking agent in the said mixture is in the range from 8:1 to 16:1.

6. A pharmaceutical dosage form according to any one of the preceding claims, in which the pharmaceutically active ingredient is a pharmaceutically acceptable salt of morphine, preferably morphine sulphate or morphine hydrochloride.

7. A pharmaceutical dosage form according to claim 5, which is suitable for once a day dosing.

8. A pharmaceutical dosage form according to any one of the preceding claims, in the form of a tablet or a capsule containing multiparticulates.

9. A process for preparing a dosage form according to any one of the preceeding claims comprising:-

(a) mechanically working in a high shear mixer a mixture of hydrophobic, fusible binder and a minor amount of an organic, fusible, polymeric material which in the finished dosage form is capable of functioning as a wicking agent at a speed and temperature at which the binder melts or softens and the mixture forms agglomerates;

(b) extruding the agglomerates whereby the extrudate is obtained as extruded pieces or an elongate extrudate is formed into pieces;

(c) continuing mechanically working the pieces in a high shear mixer; and

(d) continuing mechanically working with additional binder material at a temperature and speed at which the additional binder melts or softens.

10. A process according to claim 8, wherein in stage (d) the additional binder melts or softens and binds with the particles.

11. A solid, oral, controlled release pharmaceutical dosage form which comprises a pharmaceutically active ingredient having a solubility in water of greater than 1gm in 250ml water at 25°C dispersed in a matrix, the dosage form being obtainable by a process as defined in claim 9 or claim 10.